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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/572,563

05/09/2008

Jiunn-Liang Ko

8964-000031/US

5069

30593

7590

03/11/2011

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

03/11/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/572,563	<b>Applicant(s)</b> KO ET AL.	
	<b>Examiner</b> ALBERT NAVARRO	<b>Art Unit</b> 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-8,11,12,17,19-21 and 24-30 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,5-8,11,12,17,19-21 and 24-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 1, 2011 has been entered.

All grounds of rejection in the Office Action mailed June 28, 2010 are withdrawn.

The following new grounds of rejection are applied to the amended claims:

### ***Specification***

1. 37 CFR 1.821-1.825 requires every nucleotide of 10 or greater nucleotides to have a sequence identifier. Applicants attention is directed to paragraph 36 of the instant specification which contains a sequence larger than 10 nucleotides but lacks an appropriate SEQ ID TAG as required by 37 CFR 1.821-1.825. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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2. Claims 29-30 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Evans et al in light of Murasugi et al.

The claims are directed to a method of modulating immunological activities comprising orally administering fungal immunomodulatory protein or protein fused with FIP to a subject, wherein the fungal immunomodulatory protein is encoded by a nucleic acid molecule including SEQ ID NO: 1.

Evans et al (US Patent Number 5,928,896) disclose of compositions of immunomodulatory peptides comprising Ling-Zhi-8 for oral administration. (See Immunomodulator peptides section).

Murasugi et al (Journal of Biological Chemistry Vol. 256, No. 4, pp 2486-2593, 1991) disclose of the amino acid sequence of Ling-Zhi-8. (See page 2489).

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L28_GXLU0
ID L28_GXLU0 Revised: 111.1A.
AC P11940;
DT 01-APR-1990, integrated into TrEMBL/Swiss-Prot.
DT 25-JAN-2017, sequence version 3.
DT 17-APR-2010, entry version 37.
DE UniProtKB: Full-length immunomodulatory protein Ling Zhi-8;
DE Short-LZ-8;
OS Ganoderma lucidum [ling zhi medicinal fungus (Bracket fungus)].
OC Eukaryota: Opisthokonta: Basidiomycota: Agaricomycotina:
OC Agaricomycetes: Polyporales: Ganodermataceae: Ganoderma.
OX NCBI TaxId=53315;
RN [1]
RA MULLERBUCH SEUNGKUN [JANGHU CHAI];
RX MEDLINE=51116875; PubMed=1993000;
SA Nakazumi A., Tanabe T., Komiya H., Iwata N., Kino K., Tamoto M.,
SA Sekuma S.;
ET "Molecular cloning of a cDNA and a gene encoding an immunoregory
ET protein, Ling Zhi-8, from a fungus, Ganoderma lucidum."
ET C. Biol. Chem. 266(24):24901-24911(1991).
EW [1]
EP PROTEIN SEQUENCE OF 3-111.
EX MEDLINE=IF000248; PubMed=2573700;
LA Fushita S., Ko R., Kino K., Yoshida A., Yokochino A., Murakami A.,
EA Sekuma S., Tsunio H.;
ET "Cloning and full length sequence of an immunomodulatory protein, ling
ET zhi-8 (LZ-8), An immunomodulator from a fungus, Ganoderma lucidum,
ET having similarity to immunoglobulin variable regions."
ET C. Biol. Chem. 269(16):9372-9377(1994).
CC -!- SWISSPROT: belongs to the fungal immunomodulatory proteins (FIP)
CC family.
CC .....
CC Copyrighted by the UniProt Consortium, see http://www.uniprot.org/terms.
CC Distributed under the Creative Commons Attribution license (http://creativecommons.org/licenses/by/4.0/).
CO
CR EXEL: MS0192; AAA33350.1(-); Ganoderma_FIM.
CR FIS: AGO'10; GIVEFN.
CR UCS: 3PVS X-ray; 2JJ-A; A/S-1 All.
CR RESUM: IFSH; -.
CR RefSeqCDS:P01281; P14545; -.
CR U: BIRD_00460; Cratichneumonidae; KcsInterPro.
CR GO: 004012683; Regulation of immune system process; IMM; InterPro.
CR InterPro: IPB015339; Immunomodulatory_FIP-Fve_fam.
CR Pfam: PF0859; Phe; 1.
CR PfDom: D0U3055; Immunomodulatory_FIP_Fve_fam; 1.
CR SCOPfam: 05710152; Immunomodulatory_FIP-Fve_fam; 1.
RE 1: Evidence at protein level;
SU 3D structures: Acetylation Direct protein sequencing.
FT INIT MET 1 1 Phenol.
FT CHRIS 2 111 Immunomodulatory protein Ling Zhi-8.
FT ATTA-PFI 000104539.
FI NUCRES 2 2 A octylsuccinate.
FI RELEI: 3 14
FI STRAND 15 20
FI ST-AND 36 41
FI STRAND 49 54
FI STRAND 73 75
FI UNITE 77 80
FI STRAND 82 87
FI TURN 99 101
FI STRAND 104 110
SU SAURUCK 11 92; 12-ED RMS; 2043-EUPUE3/SER UC-691

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[illegible]

As shown above, SEQ ID NO: 1 of the instant invention encodes with 100% identity the Ling Zhi-8 protein. Accordingly, the disclosure of Evans et al of a composition for oral administration comprising the Ling Zhi-8 protein (protein encoded by a nucleic acid molecule including SEQ ID NO: 1) is deemed to anticipate each and every limitation of the instantly filed claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALBERT NAVARRO whose telephone number is (571)272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/  
Primary Examiner, Art Unit 1645  
March 9, 2011